

§ 522.2471

dogs and cats. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 15328, Apr. 9, 1982, as amended at 51 FR 24142, July 2, 1986]

§ 522.2471 Tilmicosin phosphate injection.

(a) *Specifications.* Each milliliter contains 300 milligrams of tilmicosin base as tilmicosin phosphate.

(b) *Sponsor.* See 000986 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.735 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* 10 milligrams per kilogram body weight.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Pasteurella haemolytica*. For the control of respiratory disease in cattle at high risk of developing BRD associated with *P. haemolytica*.

(iii) *Limitations.* For use only in cattle as a single subcutaneous injection. Not for human use. Use of this antibiotic in humans may prove fatal. Do not use in automatically powered syringes. Do not inject more than 15 milliliters per injection site. If no improvement is noted within 48 hours, the diagnosis should be reevaluated. Do not use intravenously in cattle. Intravenous injection in cattle will be fatal. Do not use in other animal species. Injection of this antibiotic has been found to be fatal in swine and nonhuman primates, and it may be fatal in horses. Safety of use in pregnant and breeding animals has not been established. Do not use in female dairy cattle 20 months of age or older. Use of this antibiotic in this class of cattle may cause milk residues. Do not slaughter within 28 days of last treatment. Federal law restricts this drug to use or on the order of a licensed veterinarian.

(2) [Reserved]

[57 FR 12712, Apr. 13, 1992, as amended at 62 FR 5526, Feb. 6, 1997; 63 FR 7701, Feb. 17, 1998; 63 FR 14818, Mar. 27, 1998]

§ 522.2474 Tolazoline hydrochloride injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains

21 CFR Ch. I (4–1–01 Edition)

tolazoline hydrochloride equivalent to 100 milligrams of base activity.

(b) *Sponsor.* See No. 061690 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is used as follows:

(1) *Horses*—(i) *Amount.* Administer slowly by intravenous injection 4 milligrams per kilogram of body weight or 1.8 milligrams per pound (4 milliliters per 100 kilograms or 4 milliliters per 220 pounds).

(ii) *Indications for use.* For use in horses when it is desirable to reverse the effects of sedation and analgesia caused by xylazine.

(iii) *Limitations.* The safety of Tolazine™ has not been established in pregnant mares, lactating mares, horses intended for breeding, foals, or horses with metabolically unstable conditions. The safety of Tolazine™ has not been evaluated for reversing xylazine used as a preanesthetic to a general anesthetic. This drug is for use in horses only and not for use in food-producing animals. Users with cardiovascular disease (for example, hypertension or ischemic heart disease) should take special precautions to avoid accidental exposure to this product.

Accidental spillage on the skin should be washed off immediately with soap and water. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[61 FR 25785, May 23, 1996]

§ 522.2476 Trenbolone acetate.

(a) *Specifications.* Each pellet for implanting contains 20 milligrams of trenbolone acetate.

(b) *Sponsors.* See 012579 in § 510.600(c) of this chapter for use as in paragraphs (d)(1)(i), (d)(2)(i), and (d)(3) of this section. See 021641 in § 510.600(c) of this chapter for use as in paragraphs (d)(1), (d)(2), and (d)(3) of this section.

(c) *Related tolerances.* See § 556.739 of this chapter.

(d) *Conditions of use*—(1) *Heifers.* (i) 200 milligrams trenbolone acetate (10 pellets of 20 milligrams each) for increased rate of weight gain and improved feed efficiency in growing-finishing feedlot heifers, use last 63 days prior to slaughter.